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From: Victor Donahue

Department Name:	Patent Department	Charge No.:	88424
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Telephone: (212) 733-2739

Date: December 5, 2005	Time (New York)
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COMMENTS

Re: PC10228B US

Patent Application
Attorney Docket No. PC10228B US

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By _____
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION OF: Farzan Rastinejad, et al. :

APPLICATION NO.: 09/863,976 : Examiner: Cybille Delacroix Muirheid
FILING DATE: May 23, 2001 : Group Art Unit: 1614
TITLE: METHODS AND COMPOSITIONS FOR :
RESTORING CONFORMATIONAL STABILITY
OF A PROTEIN OF THE p53 FAMILY

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Request for Clarification and Interview

Per Applicant's telephone message of November 30, 2005, a brief telephonic interview is requested in regard of the above-identified application. Although Applicant will proceed by way of an RCE submission, the disposition of the claims on the "Office Action Summary" of the Official Action mailed September 20, 2005 appears incomplete, or otherwise in some way inconsistent with the totality of the rejections that are presently made (or remain of record) in view of the objections that are also listed. Applicant would like to clarify this so that the RCE is responsive. For convenience, a copy of the Official Action is attached.

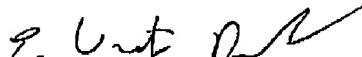
Specifically, it appears from the "Office Action Summary" sheet that there are several claims that are only objected to, and not rejected. The Examiner has also indicated that Claim 43 is allowable if written in independent form, and Applicant wonders if this disposition was also intended for any of the other claims that appear, on the face of things, only to be objected to.

Clarification is respectfully requested. Applicant expresses no view as to whether this clarification requires the re-mailing/re-dating of a corrected Official Action. It would seem that if an informal understanding could be had, Applicant would just include a confirmatory recitation of the intended official disposition of the claims in the subsequent RCE submission, and which recitation the Examiner could later validate as what was intended.

USERS\DOCS\LA21952\PEVD\591x011.DOC / 255453 / PC10228B Req. for Clarification 12/5/2005

Patent Application
Attorney Docket No. PC10228B US

Respectfully submitted,



E. Victor Donahue, Esq.
Attorney for Applicant(s)
Reg. No. 35,492

Date: December 05, 2005

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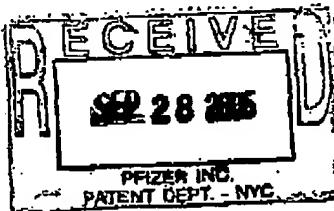


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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,976	05/23/2001	Farzan Rezendejed	PC102288	1819

7390
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EXAMINER	
DELACROIX MURIEL, CYBILLE	
ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 09/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

EHS

Office Action Summary	Application No.	Applicant(s)
	09/863,978	RASTINEJAD ET AL
	Examiner Cybille Delacroix-Muirheid	Art Unit 1614

— The MAILING DATE of this communication appears on the cover sheet with the correspondence address —
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extension of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on Dec. 3, 2004; March 21, 2005; 07/05/05.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 26-56 is/are pending in the application.
- 4a) Of the above claim(s) 56 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 26-42,44,45,47 and 54 is/are rejected.
- 7) Claim(s) 43,46,48-53 and 55 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other. _____

S-6

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Art Unit: 1614

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Detailed Action

The following is responsive to applicant's amendment/remarks received Dec. 3, 2004, March 21, 2005 and Jul. 5, 2005.

Claims 1-25 are cancelled. No new claims are added. Claims 26-56 are currently pending.

The previous claim objections set forth in paragraph 1 of the office action mailed June 3, 2004 are withdrawn in view of applicant's amendment(s) and remarks contained therein.

The previous claim rejection under 35 USC 112, first paragraph, set forth in paragraph 2 of the office action mailed June 3, 2004 is withdrawn in view of applicant's amendment(s) and remarks contained therein.

The previous rejections of claims 38, 41, 42, 43 under 35 USC 112, second paragraph, set forth in paragraphs 3 and 5-8 of the office action mailed June 3, 2004 are withdrawn in view of applicant's amendment(s) and remarks contained therein. PLEASE NOTE: the rejection of claim 28 under 35 USC 112, second paragraph (paragraphs 3-4 of the office action mailed June 3, 2004) is maintained. Claim 28 continues to recite "measurement" which has no antecedent basis in the claim.

Applicant's arguments traversing the previous claim rejection under 35 USC 102(e) and the previous claim rejection under 35 USC 103(a), set forth in paragraphs 9-10 of the office action mailed June 3, 2004 have been considered but are not found to be persuasive.

Said rejections are maintained essentially for the reasons given previously in the office action mailed June 3, 2004 with the following additional comment.

Applicant argues that in the present invention, applicant has made the pioneering discovery that small organic compounds present in doses that are small and safe enough to be

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administered to living patients can successfully rescue the conformation of p53 protein in order to facilitate treatment of cancer. Applicant further argues,

"The present invention defines methods (see independent Claim 26) which include the obvious practical limitation that the identified compounds are actually "useful in the treatment of cancer" and can usefully bind to p53 under physiological conditions. Compound X (Example 3, page 47) is such a compound. The Welch disclosure is readily seen as being not particularly relevant to the discovery of compounds that are useful as drugs, particularly those that likely bind to specific sites in the p53 protein. Rather the Welch disclosure relates to the well recognized field that proteins can be solubilized or "stabilized" by soaking in them in solvents, at immense concentrations of solvents and usually via generalized solvation effects."

"The Welch disclosure does not pertain to providing specific compounds useful as safe low dose pharmaceuticals, i.e. clinically useful sub-micromolar quantities. Simply stated, the generalized history of protein solvation experiments has nothing to do with the development of useful pharmaceuticals, nor can it, in any way, provide motivation for such other inventions or even remotely suggest predict that such useful inventions would be remotely possible. Welch fails, as it must, to suggest specific binding effects useful at physiological concentrations. It must be reiterated that the cells in patients' living bodies are very different from the cells in the in vitro cultures of Welch."

Said arguments have been considered but are not found to be persuasive. The examiner respectfully submits that applicant's arguments are not commensurate in scope with the claimed method. Applicant's claims are directed to a method of identifying organic non-peptide compounds useful in the treatment of cancer. They do not require the therapeutic treatment of a patient suffering from cancer.

Moreover, the phrase at line 2 of claim 26, "useful in the treatment of cancer" is essentially an intended use limitation. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 370 F.2d 576, 152 USPQ 235 (CCPA 1967) and In re Otto, 312 F.2d 937, 939, 136 USPQ 458, 459 (CCPA 1963) (The claims were directed to a core member for hair curlers and a process of making a core member for hair curlers. Court held that the intended use of hair curling was of no

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significance to the structure and process of making.). In this case, the intended use of treating cancer with the identified non-peptide organic compound is of no significance to the method of identifying the organic non-peptide compound. It is for these reasons as well as those submitted previously in the office action mailed June 3, 2004 that the rejections are maintained.

Claim 43 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Claims 26-42, 44-45, 47, 54 stand rejected.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Cybille Delacroix-Muirheid** whose telephone number is 571-

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272-0572. The examiner can normally be reached on Mon-Thurs. from 8:30 to 6:00 as well as every other Friday from 9:30-6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CDM *UM*
Sep. 19, 2005

Rebecca Cook
REBECCA COOK
PRIMARY EXAMINER
GROUP 4000/614

DEC 1 2001

INFORMATION DISCLOSURE CITATION								ATTY. DOCKET NO. PC102288	SERIAL NO. 09/863,976			
(Use several sheets if necessary)								APPLICANT FARZAN RASTINEJAD, et al.				
								FILING DATE May 23, 2001	GROUP 1614			
U.S. PATENT DOCUMENTS												
EXAMINER INITL.	DOCUMENT NUMBER							DATE	NAME	CLASS	SUBCL. ASS	FILING DATE OF DOCUMENT
CN	5	9	0	0	3	6	0	5/4/00	Welch, et al.			
	6	2	7	0	8	5	4	8/7/2001	Welch, et al.			
	6	3	5	9	0	0	0	3/19/2002	Jiang, et al.			
	6	3	7	2	7	6	5	4/18/02	Huang			
	6	3	8	4	0	6	9	5/7/02	Cantrell			
	6	3	8	7	6	7	3	5/14/02	Evans, et al.			
	6	3	8	7	9	0	3	5/14/02	Dinsmore, et al.			
	6	3	8	8	1	3	1	5/14/02	Medina, et al.			
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	6	3	9	1	3	0	2	5/21/02	Wallace, et al.			
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	6	3	9	1	8	5	3	5/21/02	Greene, et al.			
	6	3	9	1	9	1	6	5/21/02	Dai, et al.			
	6	3	9	2	0	6	3	5/21/02	All, et al.			
	6	3	9	5	7	2	9	5/28/02	Forzaz, et al.			
	6	3	9	5	7	4	9	5/28/02	Li, et al.			
	6	3	9	5	7	7	1	5/28/02	Ramadoss, et al.			
	6	3	9	9	5	6	3	6/4/02	Yilmazko, et al.			
	6	3	9	9	5	9	8	6/4/02	Pilkul, et al.			
	6	3	9	9	6	3	8	6/4/02	Vila, et al.			
	6	3	9	9	6	5	3	6/4/02	Henke			
	6	3	9	9	6	4	7	6/4/02	Kalpukar, et al.			
	6	4	0	3	5	5	4	6/11/02	Stratchenok, et al.			
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	6	4	0	3	5	9	2	6/11/02	Howard			
	6	4	0	3	6	2	5	6/11/02	Nagao, et al.			
	6	4	0	6	6	9	9	6/16/02	Wood			
	6	4	1	0	0	2	9	6/25/02	Mukhopadhyay, et al.			

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FOREIGN PATENT DOCUMENTS

DOCUMENT NUMBER							DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION
WO	0	2	2	4	6	9	2	3/28/02	WO	—	—
OTHER DOCUMENTS (including Author, Title, Date, Pertinent Pages, Etc.)											
<p><i>CMW</i></p> <p>Manipulating "Strategies For Manipulating the p53 pathway In treatment of human cancer" T.R. Hupp, et al. <i>Biochem J.</i> (2000), 352, pp 1-17</p> <p><i>CMW</i></p> <p>"Restoration of the tumor suppressor function to mutant p53..." V. Belyov, et al. <i>Nature Medicine</i>, Vol. 6, No. 3, March 2002</p> <p><i>CMW</i></p> <p>"p53 and IGFBP-3: Apoptosis and Cancer Protection" A. Grimbom, <i>Molecular Genetics & Metabolism</i>, 70, pp 85-89, 2000</p> <p><i>CMW</i></p> <p>"New Insights into p53 Regulation & Gene Therapy for Cancer" Alain G. Zetmet, et al. <i>Biochemical Pharmacology</i>, Vol 60, pp 1153-1163, 2000</p> <p><i>CMW</i></p> <p>"Luchtacone, a New Cell Inhibitor in p53-Transfected Cancer Cells" Rikan, et al., <i>Journal of Antibiotics</i>, Vol. 54, No. 10, pp. 850-854, Oct. 2001.</p> <p><i>CMW</i></p> <p>"Pharmaceutical Rescue of Mutant p53 Conformation & Function" Barbara Foster, et al. <i>Science</i>, Vol. 286 (12/24/99) pp2507-2510</p> <p><i>CMW</i></p> <p>"Crystal Structure of a p53 Tumor Suppressor-DNA Complex..." Yunja Cho, et al. <i>Science</i>, Vol. 265, 7/15/94, pp 348-355</p> <p><i>CMW</i></p> <p>"The Emerging p53 Gene Family" William G. Kaelin, Jr. <i>Jour. National Cancer Inst.</i>, Vol. 91, No. 7, 477/95, pp554-568</p> <p><i>CMW</i></p> <p>"Chemotherapeutic Targeting of p53" Martin L. Smith, et al. <i>Cancer Biology & Therapy</i>, Vol. 1, pp1-2, 2001</p> <p><i>CMW</i></p> <p>"Rescuing the Function of Mutant p53" Alex N. Bullock, et al. <i>Nature Reviews-Cancer</i>, Vol.1, Oct. 2001, pp68-78</p> <p><i>CMW</i></p> <p>"Oncoogenic Mutations of the p53 Tumor Suppressor" A. Sigal, et al., <i>Cancer Research</i>, 60, 6789-6793, 12/15/2000</p> <p><i>CMW</i></p> <p>"The Effects of wild-type p53 tumor suppressor activity..." C. Caldwell, et al. <i>Gene 277</i> (2001) pp 15-30</p>											

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form

REFERENCES

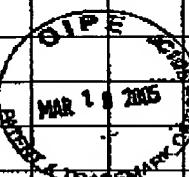
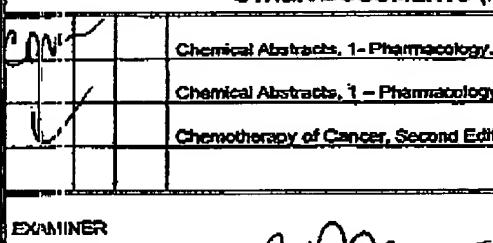
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INFORMATION DISCLOSURE CITATION <i>(Use several sheets if necessary)</i>		ATTY. DOCKET NO. PC10228B	SERIAL NO. Express Mail No. E1446402284US
REC 14 2004 U.S. PATENT & TRADEMARK OFFICE		APPLICANT Farzan Rastinejad et al.	
		FILING DATE May 23, 2001	GROUP 1624 (anticipated)
<i>CRW</i>		William Wilson, et al., "Hypoxia-Selective Antitumor Agents. 2. Electronic Effects of 4-Substituents on the Mechanisms of Cytotoxicity and Metabolic Stability of Nitroacrine Derivatives", <i>J. Med. Chem.</i> , vol. 32, pp. 31-38 (1989)	
<i>CRW</i>		T.R. Hupp, "Regulation of p53 Protein Function Through Alterations in Protein-Folding Pathways", <i>Cell Mol. Life Sci.</i> , vol. 55 pp. 88-95 (1999)	
<i>CRW</i>		K. Sakagami et al., <i>Chemical Abstracts</i> , vol. 24, No. 25, June 17, 1996, Abstract No. 332043	
		M. Watanabe et al., <i>Chemical Abstracts</i> , vol. 128, 1998, Abstract No. 175800	
		M. Watanabe et al., <i>Chemical Abstracts</i> , vol. 128, No. 14, April 6, 1998, Abstract No. 162617	
<i>CRW</i>		T. Ohmichi, et al., "Restoration of Mutant TP53 to Normal TP53 Function by Glycerol as a Chemical Chaperone", <i>Radiation Research</i> , vol. 151, no. 4 pp. 498-500 (1999)	
EXAMINER		DATE CONSIDERED	
<i>CRW</i>		9-19-05	

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DEC 1 4 2001 U.S. PATENT & TRADEMARK OFFICE			APPLICANT Farzan Rastinejad et al.	FILING DATE May 23, 2001			
			GROUP 162C 1614				
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							YES NO
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
CM	G. Selivanova, et al., <i>Nature Medicine</i> , 3, pp. 632-638, 1997						
CM	R. K. Brachmann, et al., <i>The EMBO Journal</i> , 17, pp. 1847-1859, 1998						
CM	P. V. Nikolskaya, et al., <i>Proceedings of the National Academy of Science, USA</i> , 95, pp. 14675-14680, 1998						
CM	Ted R. Hipp, et al., <i>Cell</i> , Vol. 83, pp. 237-245, 1995						
CM	B. A. Foster, et al., <i>Science</i> , Vol. 288, pp. 2307-2310, 1999						
CM	Rebecca L. Rawls, <i>Chemical and Engineering News</i> , pp. 38-41, issue of February 17, 1997						
CM	Alex N. Bullock, et al., <i>Oncogenesis</i> , 19, pp. 1245-1256, 2000						
CM	Yun-ja Cho, et al., <i>Science</i> , 265, pp. 346-355, 1994						
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)							
EXAMINER	DATE CONSIDERED						
CM	9-15-05						



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			APPLICANT FARZAN RASTINEJAD							
			FILING DATE May 23, 2001		GROUP 1614					
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2	0	0	0	3	2	1	6/2000	WO	514	259
Cited	By	Examiner								
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)										
CIN	Kaneko et al., Cancer Letters. (1995), 91/1 (11-17) Abstract Only									
CIN	Carter, et al., Chemotherapy of Cancer, Second Edition, John Wiley & Sons, N.Y., N.Y., August 13, 1981, pp 67, 98 & 362-365									
CIN	Foster et al., Science (1999), 286(5449), 2507-2510 ABSTRACT ONLY									
CIN	Brown, et al., "Chemical Chaperones Correct The Temperature Sensitive Protein Folding Defects Associated With p53 and Ubiquitin," Mol. Biol. Cell, Vol. 7, December 1996; page 337a; Abstract 1996									
EXAMINER	DATE CONSIDERED							9-19-05		
Initials: <i>Com</i>										
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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)									
		Chemical Abstracts, 1- Pharmacology, Vol. 128, No. 14, 1998, No. 162831							
		Chemical Abstracts, 1 - Pharmacology, Vol. 128, No. 15, 1998, No. 175800							
		Chemotherapy of Cancer, Second Edition John Wiley & Sons, New York, pp. 87, 89, 362-365, 1981.							
EXAMINER <u>John W. Schowalter</u>		DATE CONSIDERED <i>CMM</i>			9-19-05				
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Conforms with FORM PTC-FD-A820

INFORMATION DISCLOSURE

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INFORMATION DISCLOSURE CITATION LIST.DOT, 3/98

(Use several sheets if necessary)		APPLICANT	Farzan RASTINEJAD				
		FILING DATE	May 23, 2001				
					GROUP	1614	
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<i>CM</i>	M. Demma et al., J. Biol Chem. Papers In Press. Published on August 11, 2004 as Manuscript M401854200, "CP-31398 Restores DNA Binding Activity to Mutant p53 <i>in vitro</i> but Does not Affect p53 Homologs p63 and p73.", JBC v. 279, pp. 45867-45888 (2004)						
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EXAMINER	<i>CM</i>			DATE CONSIDERED			
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